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PATENTS, TRADEMARKS, COPYRIGHTS, AND RELATED INTELLECTUAL PROPERTY MATTERS

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OUR FILE NO.
MCRVT-023C

FACSIMILE COVER SHEET

Date: September 17, 2004

To: **Mail Stop Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Facsimile: 703-872-9306

Re: U.S. Patent Application No. 09/758,832
Applicant: Horton
Title: Insitu Formable and Self-Forming Intravascualr Flow Modifier (IFM), Catheter and IFM Assembly and Method for Deployment of Same

From: Robert D. Buyan, Reg. No. 32,460

Total Number of Pages: 8 (including this form). Please notify us immediately if you have not received all pages.

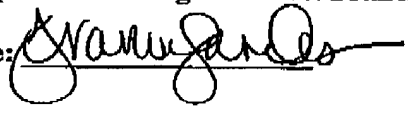
Message:

Attached is a corrected version of the previously filed Lenker Declaration. We have corrected erroneous paragraph numbering, inserted the inadvertently omitted word "Limon" in paragraph 6 and added a date line next to the signature line.

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence for Serial No. 09/758,832 is being facsimile transmitted to the Mail Stop Amendment, Commissioner for Patents at (703) 872-9306 on September 17, 2004.

Name of person sending facsimile: Francine Sanders, Assistant

Signature: 

Attorney Docket No. MCRVT-023C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Horton, et al.	Art Unit: 3731
Application No. 09/758,832	Examiner: Thaler, M.
Filed: January 11, 2001	
For: Insitu Formable and Self-Forming Intravascular Flow Modifier (IFM) and IFM Assembly for Deployment of Same	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REVISED DECLARATION OF JAY ALAN LENKER, Ph.D. PURSUANT TO 37 C.F.R. §1.132

Sir:

I, Jay Alan Lenker, do hereby declare as follows:

1. I hold bachelor's, master's and Ph.D. degrees in engineering from the Pennsylvania State University and have twenty-five (25) years of experience in the fields of biomedical engineering and medical device research and development. Specifically, I have been directly involved in research and development relating to artificial hearts & left ventricular assist devices, blood oxygenators and other cardiopulmonary bypass-related devices, prosthetic heart valves, devices and methods for treatment of benign prostatic hypertrophy and other urological disorders, stents, endovascular grafts, catheters, less invasive treatments for cerebral aneurysms and occlusive disorders, minimally invasive direct cardiac massage devices, and numerous other medical devices. I have been employed by and/or retained and a consultant to a number of medical device companies including Baxter Travenol Laboratories, Inc., Shiley, Inc., ASI, Inc., Medtronic AneuRx, Inc., MicroTherapeutics, Inc., Thera Cardia, Inc. I was also a consultant to MicroVention, Inc., the owner of the above-identified patent application, from August 1996 to August 1997, during which I gained an understanding of their developmental programs relating to the treatment of cerebrovascular aneurysms.

2. I am named as an inventor in over sixty (60) issued United States Patents and numerous pending patent applications.

3. I have been provided with, and have read, a copy of the above-identified United States Patent Application Serial No. 09/758,832 entitled "Insitu Formable and Self-Forming Intravascular Flow Modifier (IFM) and IFM Assembly for Deployment of Same" (hereinafter referred to as the "subject patent application").

4. I have also been provided with, and have read, the amended patent application claims appended hereto as Appendix A.

5. I have also been provided with, and have read, copies of the following: United States Patent No. 4,512,338 (Balko), United States Patent No. 5,122,136 (Guglielmi et al.), United States Patent no. 5,476,505 (Limon) and Massoud, Tarik F., Turjman, Francis, Ji, Cheng, Vinuela, Fernando, Guglielmi, Guido, Gobin, Y. Pierre, AND Duckwiler Gary R., *ENDOVASCULAR TREATMENT OF FUSIFORM ANEURYSMS WITH STENTS AND COILS: TECHNICAL FEASIBILITY IN A SWINE MODEL*, Am J Neuroradiol, 16:1953-1963, November 1995.

6. As of June 21, 1996, the date on which the subject patent application was filed, I do not believe that the methods recited in the amended patent application claims appended hereto as Appendix A would have been obvious to an ordinarily skilled person engaged in the design and development of catheter-based devices and methods for the treatment of cerebrovascular defects such as aneurysms, even if such person had read the Balko, Guglielmi et al., Limon and Massoud et al. references listed in Paragraph 4 above.

7. Prior to June 21, 1996, it was common for implantable cerebrovascular occlusion coils, such as the device described in United States Patent No. 5,122,136 (Guglielmi et al.), to be attached to a portion of the delivery catheter system by way of a releasable connection that remains in tact until the operator volitionally causes the releasable connection to be severed or released. In fact, a number of currently marketed implantable cerebrovascular occlusion coils incorporate such releasable connections. The use of such releasable connections on occlusion coils is desirable because, if the occlusion coil is implanted in other than its

intended location (e.g., within the lumen of a blood vessel through which blood flows), it may result in undesirable or even catastrophic occlusion of blood flow. However, prior to June 21, 1996 it was not, to my knowledge, known for any stent or other implantable device that assumes a generally tubular shape having a hollow flow channel therethrough when implanted in the lumen of a blood vessel to incorporate such a releasable connection. In fact, the motivation to utilize a releasable connection on an occlusion coil to prevent undesirable or catastrophic accidental occlusion of a blood vessel does not generally apply to stents or other tubular implants that allow blood flow therethrough, because those stents and other tubular implants are not configured to substantially block blood flow in the manner of an occlusion coil.

8. Prior to June 21, 1996, although there were various cerebrovascular occlusion coils with releasable connections and various cerebrovascular stents without releasable connections available on the market, to the best of my knowledge, no stent having a releasable connection was then available on the market or described in the literature.

9. I believe that, if ultimately used in clinical medicine, the invention described in the subject patent application and recited in the amended claims attached hereto as Appendix B would provide a substantial advancement in the state of the art and would satisfy a long felt need in the art by providing a system for embolization of cerebrovascular aneurysms with reduced potential for migration or protrusion of the embolic member (e.g., occlusion coil) from the aneurysm and into the true lumen of the adjacent blood vessel.

I hereby declare that all statements made herein are believed to be true and all statements made on information and belief are believed to be true and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

20 Aug 2004
Date

Jay Alan Lenker, Ph.D.